

Docket No.: A8130.0028/P028-A
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Reinhold Schmieding

Application No.: 10/665,480

Confirmation No.: 5525

Filed: September 22, 2003

Art Unit: 3738

For: IMPLANT FOR CROSS-PIN ACL
RECONSTRUCTION (AS AMENDED)

Examiner: Christopher D. Prone

APPELLANT'S REPLY BRIEF

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Madam:

This is a Reply Brief pursuant to 37 C.F.R. § 41.41 in response to the Examiner's Answer mailed October 28, 2008 in connection with the appeal from the final rejection of claims 10-15 mailed October 24, 2007 in the above-identified U.S. patent application.

A. Total Number of Claims in Application

There are 6 claims pending in application. The application contains claims 10-15, which were finally rejected. This is an appeal from the final rejection of claims 10-15.

B. Current Status of Claims

1. Claims canceled: 1-9
2. Claims withdrawn from consideration but not canceled: None
3. Claims pending: 10-15
4. Claims allowed: None
5. Claims rejected: 10-15

C. Claims On Appeal

The claims on appeal are claims 10-15.

II. GROUND OF REJECTION TO BE REVIEWED ON APPEAL

Whether the rejection of claims 10-15 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement, is ripe for appeal.

Whether the rejection of claims 10, 11 and 13-15 as being unpatentable over Grooms (Int. Application Pub. WO 99/21515) ("Grooms") in view of Chow (U.S. Patent No. 5,176,682) should be reversed.

Whether the rejection of claim 12 as being unpatentable over Grooms in view of Chow and further in view of Grooms et al. (U.S. Patent No. 6,045,554) ("Grooms '554") should be reversed.

III. ARGUMENT

Although the Examiner's Answer does not raise any new grounds for rejection, Appellant briefly responds to the Examiner's remarks regarding Appellant's arguments in the Appeal Brief. Appellant incorporates all comments from Appellant's Amended Appeal Brief, dated July 22, 2008. Appellant provides the following comments in response to the Examiner's arguments on pages 3-6 of the Examiner's Answer.

A. CLAIMS 10-15, AS AMENDED, COMPLY WITH THE WRITTEN DESCRIPTION REQUIREMENT

Appellant submits that the issue of whether claims 10-15 comply with the written description requirement is not ripe for appeal, and that, even if it would be, the issue is moot as applicant has filed an amendment deleting the term "rigid" (on which the rejection of these claims is based upon).

In the Amendment in Response to Final Office Action dated January 23, 2008, claim 10 was amended to delete the term "rigid" from lines 11 and 12. The amendment to claim 10 (deleting the term "rigid") was filed in response to the final rejection of claims 10-15 under 35 U.S.C. § 112, as failing to comply with the written description requirement (as the term "rigid" was not supported in the specification).

Appellant submits that MPEP § 714 II. clearly provides that:

(D) [For] An **after-final amendment**, the amendment will be forwarded in unentered status to the examiner. In addition to providing reasons for non-entry when the amendment is not in compliance with 37 CFR 1.116 (e.g., the proposed amendment raises new issues that would require further consideration and/or search), the examiner should also indicate in the advisory action any non-compliance in the after-final amendment.

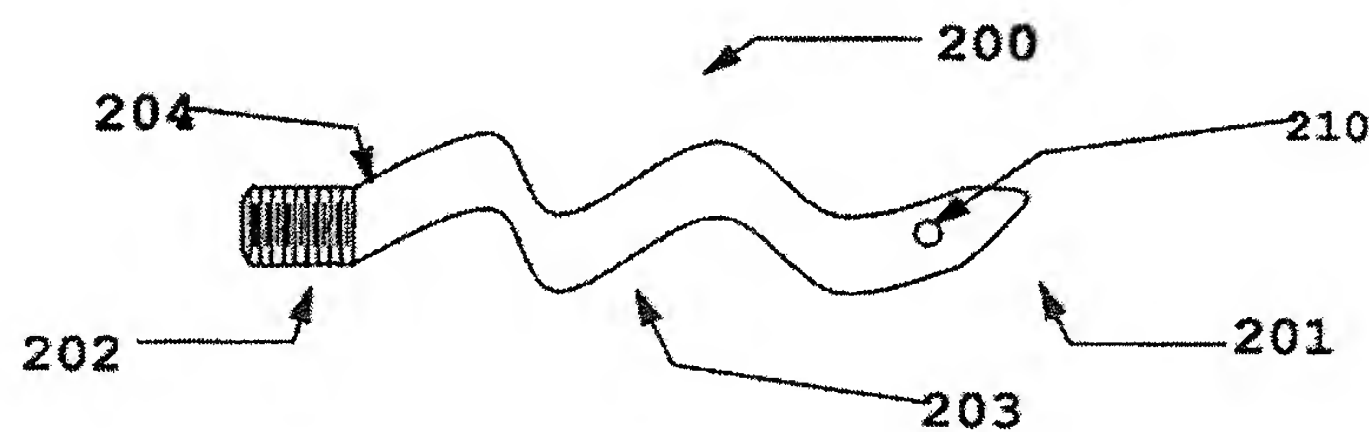
MPEP § 714 II. (emph. added)

In the Advisory Action dated February 14, 2008, the Examiner -- inexplicably -- refused to enter this Amendment. The Examiner failed to provide reasons of why the entry of the amendment was not effectuated or whether the amendment was improper, and also failed to provide reasons of any non-compliance in the After Final Amendment indicated in the Advisory Action. In the Examiner's Answer dated October 28, 2008, the Examiner further failed to provide any reasons for the non-entry of the amendment to claim 10. Appellant submits that, upon proper entry of the Amendment deleting the term "rigid" from claim 10, claims 10-15 will comply with the written description requirement of 35 U.S.C. § 112, and the issue is therefore moot.

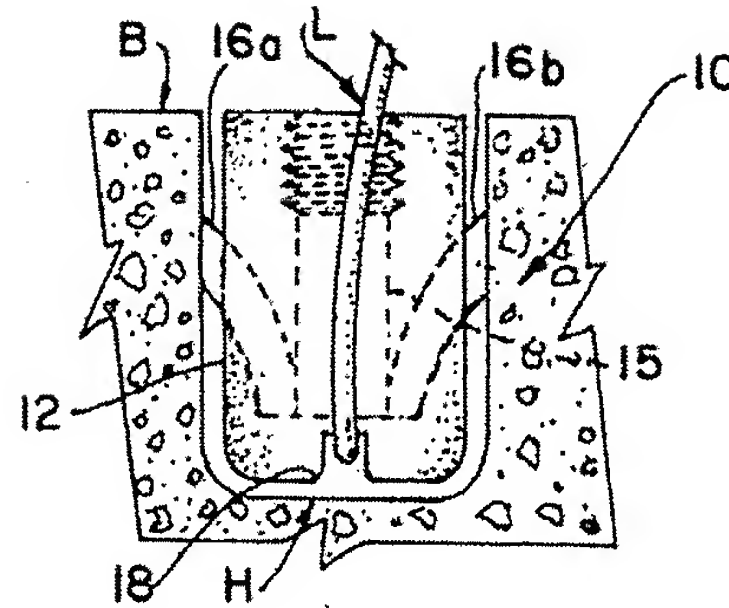
B. THE SUBJECT MATTER OF THE CLAIMED INVENTION IS PATENTABLE
OVER GROOMS AND CHOW

Claims 10, 11 and 13-15 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Grooms (Int. Application Pub. WO 99/21515) (“Grooms”) in view of Chow (U.S. Patent No. 5,176,682).

Grooms fails to disclose or suggest any channels in communication with an eye, much less in communication with a transverse eye. As illustrated in Fig. 2B of Grooms (reproduced below), Grooms teaches a mineralized bone segment 202 and a flexible, demineralized segment 203 with a “fixation hole 210” (page 4, line 29).



Chow is cited as disclosing channels, but Chow does not disclose or suggest channels “extending completely from the transverse eye to the tip.” As shown in Fig. 1 of Chow (reproduced below), Chow does not disclose or suggest an implant for “cross-pin anterior cruciate reconstruction surgery” with “a tapered distal end,” much less an implant for “cross-pin anterior cruciate reconstruction surgery” with “a tapered distal end” and also with channels “extending completely from the transverse eye to the tip,” as claim 10 recites.



In the Examiner's Answer dated October 28, 2008, the Examiner asserts that "[I]t would have been obvious . . . [to] use the tapered channels surrounding the through hole taught by Chow on the implant of Grooms" (Examiner's Answer at 4). Appellant disagrees with this assertion for at least the following reasons:

First, Chow does not disclose any implant with a "through hole." Surgical implement 10 of Chow is provided with fins 16a, 16b and a recess 18 to allow ligament L to be caught in the recess 18 before insertion into a hole. However, recess 18 of Chow is not a "through hole" or an "eye" provided through a "tapered distal end" and is not "extending completely through said tapered distal end," as in the claimed invention. Because of its configuration (designed specifically for ligament positioning), the recess 18 of Chow is also not a "transverse eye," much less a "transverse eye for receiving a flexible strand," or a "transverse eye for receiving a flexible strand to draw said implant into an opening in bone," as claim 10 recites.

Second, channels 20a, 20b of Chow are clearly not "extending completely from the transverse eye to the tip." These channels are not in communication with a transverse eye and, thus, they cannot be extending from a transverse eye to the tip of the implant. Thus, even if *arguendo* Grooms teaches an eye and even if *arguendo* Chow teaches longitudinal channels, the combined references still do not disclose or suggest an eye with channels "extending completely from the transverse eye," as in the claimed invention (emph. added).

Third, a person skilled in the art would not have been motivated to combine the teachings of Grooms (regarding an “eye”) with those of Chow (regarding a “channel”). Grooms teaches a bone implant having a rigid, mineralized bone segment, and a flexible, demineralized segment formed by exposing the implant to a HCl solution, for example. Grooms teaches that the demineralized segment has “sufficient flexibility to act as a ligament, tendon, or flexible support” (claim 3). In contrast, the crux of Chow is a surgical implement 10 provided with fins 16a, 16b and a recess 18 (to allow ligament L to be caught in the recess 18 before insertion into a hole) and also provided with a central bore 14 (to allow hollow tool T to matingly engage implement 10 to force the fins 16a, 16b outwardly against the sidewalls of the hole). Thus, one skilled in the art would not have been motivated to combine the bone implant of Grooms (which has a demineralized segment that itself acts as a ligament or tendon between two body parts) with the surgical implement 10 of Chow (which is specifically designed to retain a ligament and which has a configuration -- with a central bore that allows a tool to engage the implement -- that allows it to rotate within a hole).

A person of ordinary skill in the art would also not have been motivated to combine the demineralized/mineralized bone segments of Grooms with the surgical implement of Chow provided with flexible fins that are “forced outwardly” into the bone hole, as the demineralized/mineralized bone segments of Grooms would not withstand any force exerted by such fins.

A person skilled in the art would also not have been motivated to combine the references as the Examiner failed to provide a reason for the combination. Appellant submits that the Supreme Court has recently held that “[t]o determine whether there was an apparent reason to combine the known elements in the way a patent claims, it will often be necessary to look to interrelated teachings of multiple patents; to the effects of demands known to the design community or present in the marketplace; and to the background knowledge possessed by a person having ordinary skill in the art” and that “[t]o facilitate review, this analysis should be made explicit.” *KSR Int’l Co. v. Teleflex Inc.*, 2007 U.S. LEXIS 4745, 9-10 (U.S. 2007). Further, it remains the policy of the United States Patent and Trademark Office that “in formulating a rejection under 35 U.S.C. 5 103(a) based upon a combination of prior art elements, it remains necessary to identify the reason why a person

of ordinary skill in the art would have combined the prior art elements in the manner claimed.”

USPTO KSR Memo, from Margaret A. Focarino, Deputy Commissioner for Patent Operations to Technology Center Directors, May 3, 2007. The Examiner has failed to provide such a reason.


The Examiner states in the Examiner's Answer that “[I]t would have been obvious to one having ordinary skill in the art . . . [to] use the tapered channels surrounding the through hole taught by Chow on the implant of Grooms in order to provide an implant that has a smoother guide surface for the suture thread around the through hole thereby relieving stress on the suture (Examiner's Answer at 4). Appellant disagrees with this statement. As discussed above, Grooms is concerned with a bone implant having a rigid, mineralized bone segment, and a flexible, demineralized segment (formed by exposing the implant to a HCl solution and which has “sufficient flexibility to act as a ligament, tendon, or flexible support”). As Grooms does not teach that suture stress on its demineralized segment is a problem, or even exists, one skilled in the art would not have been motivated to combine the teachings of Chow to solve a problem that does not exist.

IV. CONCLUSION

Claims 10-15, as amended in the unentered Amendment of January 23, 2008, comply with the requirements of 35 U.S.C. § 112, first paragraph. The Examiner's rejection of claims 10-15 on prior art grounds should be reversed for the reasons set forth above and in the Appellant's Amended Appeal Brief submitted on July 22, 2008.

Dated: December 23, 2008

Respectfully submitted,

By 

Stephen A. Soffen

Registration No.: 31,063

Gabriela I. Coman

Registration No.: 50,515

DICKSTEIN SHAPIRO LLP

1825 Eye Street, NW

Washington, DC 20006-5403

(202) 420-2200

Attorneys for Appellant